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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,744	02/02/2004	Christopher Hunter	120-000220US	4909

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EXAMINER	
WOODWARD, CHERIE MICHELLE	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/768,744	HUNTER ET AL.	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,11-13,18-23 and 73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,11-13,18-23,73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/13/2007 has been entered.

Formal Matters

2. Claims 2, 3, 4-5, 7-10, 14-17, 22-23, and 27-72 have been cancelled by Applicant. Claims 1, 6, 11-13, 18-21, 24-26, and 73 are pending and under examination.

Response to Arguments/Amendments

Priority/Benefit

3. Applicant argues that the examiner did not acknowledge the claim of benefit to provisional application 60/444,494, filed 31 January 2003, and provisional application 60/519,074, filed 10 November 2003 (Remarks, p. 7, third paragraph). Applicant's argument is unsupported by the facts in the record. The examiner specifically denied benefit to these two provisional applications for the reasons of record.

4. Regarding the **denial of benefit** to US Provisional 60/444,494, filed 31 January 2003, Applicant argues that although the provisional applications are collections of articles for publication, they fulfill the requirements of 35 USC 112 (Remarks, p. 7, last paragraph). Applicant argues that although the inventors are not authors on some of the publications included in the composite provisional filing, Applicant argues that those materials are provided merely for background support to highlight the novelty of the claimed invention (Remarks, p. 7, last paragraph to p. 8, first paragraph). Applicant argues that the publications show that one of skill in the art would not have used an agonist of IL-27R to suppress the immune system, but would have used an antagonist (Remarks, p. 8, first paragraph). Applicant also states that the claims have been amended in part in light of the denial of benefit in the prior Office Action, which discussed gene therapy and alleged that agonists are not taught in the provisional applications (Remarks, p. 8, second paragraph). Applicant requests that the examiner reconsider the benefit claim in light of the claim amendments (Remarks, p. 8, second paragraph).

Applicant argues that in provisional 60/44,494 the inventive concept that the receptor for IL-27 is involved in the control and duration and intensity of immune responses in mammals is taught at page 10, column 2, where the role of IL-27R is described and proposed as a target for immune suppression (Remarks, p. 8, last paragraph). Applicant also argues that page 5 and pages 9-10 further describe the discovery that the absence of IL-27R leads to immune hyperactivity (Remarks, p. 8, last paragraph). Applicant argues that one of skill in the art would know based on the data to activate IL-27R with an agonist to suppress the immune system (Remarks, p. 8, last paragraph). Applicant argues that the abstract clearly states that the data fully support that the receptor is an antagonist of T-cell mediated immune hyperactivity (Remarks, p. 8, last paragraph, to page 9, first paragraph). Applicant argues that one of skill in the art would know that if the receptor antagonizes or blocks immune hyperactivity, to use an agonist or activator of the receptor to suppress the immune system, as claimed (Remarks, p. 9, first paragraph). Applicant also argues that these concepts and data are reiterated in provisional application 60/519,074, e.g., at page 3, column 2 and page 10, column 2 (Remarks, p. 9, first paragraph).

Applicant argues that with regard to both provisional applications, the inventive concept is that of using an agonist of IL-27R to suppress the immune system, **"even if no particular agonists, e.g., antibodies are presented in the applications"** (Remarks, p. 9, second paragraph). Applicant argues that one of skill in the art would know how to make an agonist antibody to a known receptor (Remarks, p. 9, second paragraph). **Applicant's arguments have been fully considered, but they are not persuasive.**

Neither provisional application 60/444,494, filed 31 January 2003 nor provisional application 60/519,074, filed 10 November 2003 provide sufficient support under 35 USC 112, first paragraph to enable a person of ordinary skill in the art to practice the invention claimed in the nonprovisional application. In New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co., 298 F.3d 1290, 1294, 63 USPQ2d 1843, 1846 (Fed. Cir. 2002), the court held that for a nonprovisional application to be afforded the priority date of the provisional application, **"the specification of the provisional must contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms,' 35 U.S.C. § 112 ¶1, to enable an ordinarily skilled artisan to practice the invention claimed in the nonprovisional application."** In New Railhead, a nonprovisional application, issued as Patent No. 5,899,283, was filed within one year of the filing of the provisional application but more than one year after an offer for sale. If the '283 patent was not afforded the priority date of the provisional application, the patent would be invalid under 35 U.S.C. 102(b) since it was filed more than one year after the commercial offer for sale. The court looked at claim 1 of the '283 patent which recites a bit body being angled with respect to the sonde housing. The court then reviewed the provisional

application and concluded that **nowhere in the provisional application** is the bit body **expressly described** as "being angled with respect to the sonde housing" as recited in claim 1 of the '283 patent. The court held that the disclosure of the provisional application does not adequately support the invention claimed in the '283 patent as to the angle limitation and therefore, the 283 patent is not entitled to the filing date of the provisional application under 35 U.S.C. 119(e)(1) and the '283 patent is invalid under 35 U.S.C. 102(b).

In order for a claim in a later-filed nonprovisional application to be entitled to the benefit of the filing date of the provisional application, the written description and drawing(s) (if any) of the provisional application must adequately support and enable the subject matter of the claim in the later-filed nonprovisional application. If a claim in the nonprovisional application is not adequately supported by the written description and drawing(s) (if any) of the provisional application (as in New Railhead, *supra*), that claim in the nonprovisional application is **not** entitled to the benefit of the filing date of the provisional application. In order to receive benefit, the disclosure of the provisional application must adequately provides (1) a written description of the subject matter of the claim(s) at issue in the later-filed nonprovisional application, and (2) an enabling disclosure to permit one of ordinary skill in the art to make and use the claimed invention in the later-filed nonprovisional application without undue experimentation (see also MPEP 201.11, 37 CFR 1.78, and 35 USC 119(e)).

With regard to Applicant's argument regarding the background documents in the provisional applications in which the instant inventors are **not the authors**, these documents **do not** assist the examiner in determining benefit because they do not provide sufficient guidance or a description of the invention claimed in the pending nonprovisional application. Applicant's argument that these publications show that one of skill in the art would **not** have used an **agonist** of IL-27R to suppress the immune system, but would have used an **antagonist, is not persuasive,** as none of these papers teach the instantly claimed a method of treating a patient. Applicant's argument that these references teach away from the instant invention is not supported by the references.

Applicant's argument that in provisional 60/44,494 the inventive concept that the receptor for IL-27 is involved in the control and duration and intensity of immune responses in mammals is taught at page 10, column 2, where the role of IL-27R is described and proposed as a target for immune suppression (Remarks. p. 8, last paragraph), is not persuasive. The only thing disclosed on page 10 is that the identification of a role for WSX-1, which is only half of the IL-27R heterodimeric receptor, comprising WSX-1 and gp130, has clinical implications for T-cell mediated disorders. No methods or steps of treating a patient using an IL-27R agonist are disclosed in either provisional application.

Applicant's argument that page 5 and pages 9-10 further describe the discovery that the absence of IL-27R leads to immune hyperactivity (Remarks, p. 8, last paragraph), is noted, but the elucidation of one possible function for WSX-1 (which is only one subunit of the heterodimeric IL-27 receptor; the other subunit being gp130) does not provide sufficient disclosure or support for the instantly claimed method. At best it only provides motivation for future experimentation as to the monomeric subunit. Applicant's argument that one of skill in the art would know, based on the data, to activate IL-27R with an agonist to suppress the immune system (Remarks, p. 8, last paragraph) cannot be accepted in the absence of evidence. Page 10 of the 60/444,494 provisional application suggests a role for WSX-1 in the suppression of T-cell hyperactivity, but does not further expand on this unsupported hypothesis. Nothing on page 5 nor in the abstract (page 2 of 60/444,494) nor anything in provisional application 60/519,074 provides any additional guidance in this regard. Again, at best, the provisional application suggests an opportunity for future experimentation on the monomeric subunit, but nothing more.

Merely suggesting that one of skill in the art "would know to use an agonist or activator of IL-27R suppress the immune system" based on the limited disclosure in the provisional applications is not sufficient to meet the requirements of 35 USC 112, first paragraph such that the two provisional applications may be deemed to provide sufficient support and adequate disclosure of the claims in the instant nonprovisional application. Rather, the disclosure in the provisional applications amount to nothing more than an invitation for further experimentation. Neither provisional application provides sufficient guidance or an adequate description of the genus of IL-27R agonists such that one of ordinary skill in the art would be able to make and use them in a method of treatment, as presently claimed, without undue experimentation. As such benefit to provisional application 60/44,494, filed 31 January 2003, and provisional application 60/519,074, filed 10 November 2003, **remains DENIED**.

Applicant continues to be accorded benefit only to the **filing date of the instant application**, that of **2 February 2004.**

Claim Rejections Withdrawn

5. The rejections over claims 3, 8, 15, 22, and 23 are withdrawn as moot in light of Applicant's cancellation of the claims.

6. The rejection over claims 1, 6, 8, 11-13, 18-21, 24-26, and 73 under 35 U.S.C. 112, first paragraph, scope of enablement, is withdrawn in light of Applicant's amendments.

7. The rejection over claims 1, 6, 11-13, 18-21, 24-26, and 73 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in light of Applicant's amendments.

Claim Rejections Maintained

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 6, 11-13, 18-21, 24-26, and 73 remain rejected under 35 U.S.C. 102(a) and 35 USC 102(e) as being anticipated by Timans *et al.*, US Patent Application Publication 2002/0164609 A1 (publication date 7 November 2002) now US Patent 7,148,330 (12 December 2006, filed 30 November 2001), for the reasons of record and the reasons set forth herein.

Applicant argues that although Timans et al., teach the use of agonists in inflammatory conditions, it does not specify that agonists be used for suppression of an inflammatory condition as presently claimed (Remarks, p. 12, third paragraph). Applicant argues that although paragraph 39 of Timans et al., teaches IL-D80 or IL-28 agonists, it does not specifically teach their use to treat an immune disorder (Remarks, p. 12, paragraphs four and five). Applicant argues that the Office Action reference to paragraph 135 of Timans et al., only defines an agonist as a compound having stimulating activity and teaches that biological assays can determine whether a compound is an agonist or antagonist (Remarks, p. 13, second paragraph). Applicant argues that a generic statement indicating that antibodies to IL-27R can be made and identified and used in [treatment of] immune disorders does not teach the specific use of agonist antibodies to IL-27R as presently claimed (Remarks, p. 13, second paragraph). Applicant argues that the final sentence of paragraph 139 of Timans et al., mentions a therapeutic use for agonist antibodies, but does not state what that therapeutic use might be (Remarks, p. 13, second paragraph). Applicant argues that the art at the time the application was filed and Timans et al., as a whole, clearly

show that immune suppression was not a contemplated use [i.e. purpose] for an agonistic antibody to IL-27R (Remarks, p. 13, second paragraph). Applicant argues that paragraph 161 of Timans et al., highlights that Timans et al., advocate a role for an antagonist of IL-27R in the treatment of an inflammatory response, but that the instantly claimed methods are drawn to using an agonist of IL-27R (Remarks, p. 13, last two paragraphs). Applicant's arguments have been fully considered, but they are not persuasive.

Applicant's argument that Timans et al., does not specify that agonists be used for suppression of an inflammatory condition as presently claimed, is tantamount to arguing the intended use of the agonists. The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claims recite using an old composition or structure and the "use" is directed to a result or property of that composition or structure (i.e. as an agonist), then the claim is anticipated. In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). While the reference may not show a specific recognition of the claim result using the same language as the instant claims, it is implied and its discovery by Applicant is tantamount only to finding a property in the old composition. In re Tomlinson 363 F.2d at 934, 150 USPQ 623, at 628 (CCPA 1966).

Applicant's argument that Timans et al., would not appreciate the importance of the need for a method of treatment using an IL-27R agonist is also construed as a statement that Timans et al., would not have appreciated the intended use of an IL-27R agonist. This argument is not supportable because Timans et al., teach the administration of an agonist of IL-D80 [p28], IL-27, or WSX-1/TCCR, "in the treatment of abnormal medical conditions, including immune disorders, e.g...inflammation..." (p. 4, col 1, paragraph 0039). The agonists taught by Timans et al., include receptor [WSX/TCCR] agonists (p. 4, col 1, paragraph 0039), and agonists where the binding component comprises a Fv, Fab, or Fab2 fragment (p. 2, col 2, paragraph 0019). Additionally, Timans *et al.*, teach the therapeutic use of stimulatory antibodies as agonists (p. 12, col 2, paragraph 0135). Further, Timans *et al.*, teach the role of the receptor subunit WSX-1/TCCR in inflammatory responses (p. 15, col 2, paragraph 0161). For this reason, Applicant's arguments that Timans et al., does not teach the specific use of agonist antibodies to IL-27R as presently claimed (Remarks, p. 13, second paragraph), does not teach what that therapeutic use might be (Remarks, p. 13, second paragraph), and that immune suppression was not a contemplated use [i.e. purpose] for an agonistic antibody to IL-27R (Remarks, p. 13, second paragraph), are also not persuasive for these same reasons.

It also is noted that, like Timans et al., the instant specification and the original claims also teach the use of both IL-27R **antagonists and agonists** in the method of treating an immune disorder in a

patient. The teachings of IL-27R antagonists and agonists represent different embodiments and the teaching of one does not represent a teaching-away from the other. They are simply different embodiments of the prior art, as they are different embodiments within the present application. The instant claims remain anticipated.

10. Claims 1, 6, 11-13, 18-21, 24-26, and 73 remain rejected under 35 U.S.C. 102(b) as being anticipated by De Sauvage et al., WO 01/29070 (26 April 2001) (see also US Patent Application Publication 2004/0234522 A1) for the reasons of record and for the reasons set forth below.

Applicant argues that while agonist antibodies of IL-27R may be discussed in De Sauvage, the agonists are advocated to promote differentiation of helper T cells, not to modulate an immune response as claimed (Remarks, p. 14, third paragraph). Applicant acknowledges that any definition of immune related diseases or disorders will most likely include a suggestion of immune suppression in some situations (Remarks, p. 14, last paragraph). However, Applicant argues that De Sauvage does not teach the specific use of an agonist for immune suppression (Remarks, p. 15, first paragraph). Applicant acknowledges that while De Sauvage may teach how to make an agonist antibody to IL-27R and state that such agonists could play a role in treatment of immune disorders, Applicant argues that it does not teach or suggest that such an agonist antibody should be given to a patient in need of immune suppression (Remarks, p. 15, first paragraph). Applicant acknowledges that although De Sauvage list treatment of various inflammatory diseases on pages 8 and 9, Applicant argues that it does not specify that suppression of an inflammatory immune response should constitute treatment with an agonist of IL-27R (Remarks, p. 15, first paragraph). Applicant argues that De Sauvage teaches away from the instant invention by teaching that an agonist of IL-27R should be given to a patient in need of Th1 activation, not immune suppression as presently claimed (Remarks, p. 15, second paragraph). Applicant's arguments have been fully considered, but they are not persuasive.

Applicant's argument that De Sauvage does not specify that agonists be used for modulation of an immune response is not supported in light of Applicant's own admission that "immune suppression" is typically a *de facto* part of "any definition of an immune related disease or disorder" (Remarks, p. 14, last paragraph). Applicant's argument that De Sauvage does not teach the "specific use" of an agonist for immune suppression is tantamount to arguing the intended use of the agonists. The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claims recite using an old composition or structure and the "use" is directed to a result or property of that composition or structure (i.e. as an agonist), then the claim is anticipated. In re May,

574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). While the reference may not show a specific recognition of the claim result using the same language as the instant claims, it is implied and its discovery by Applicant is tantamount only to finding a property in the old composition. In re Tomlinson 363 F.2d at 934, 150 USPQ 623, at 628 (CCPA 1966). Applicant's argument that De Sauvage does not teach or suggest that such an agonist antibody should be given to a patient in need of immune suppression is also an argument related to an intended use. Applicant's argument that De Sauvage does not teach or suggest that such an agonist antibody should be given to a patient in need of immune suppression fails in light of the teaching by De Sauvage to treat immune related diseases using anti-TCCR (WSX-1) antibodies, including agonist antibodies (p. 3, last paragraph and pp. 51-56). Applicant's own admission that "immune suppression" is typically a *de facto* part of "any definition of an immune related disease or disorder" (Remarks, p. 14, last paragraph) contradicts Applicant's argument. De Sauvage specifically teaches methods of treatment of diseases characterized by immune hyperactivation (see pages 59-63) using TCCR (WSX-1) polypeptides and antibodies, including agonist antibodies. Additionally, De Sauvage also specifically contemplates inhibition of molecules with proinflammatory properties (i.e. immune suppression) at p. 63, line 36. The instant claims remain anticipated.

11. Claims 1, 6, 11-13, 18-21, 24-26, and 73 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al., WO 97/25425 (17 July 1997), for the reasons of record and for the reasons set forth herein.

Applicant argues that Bennett et al., discloses an IL-27 receptor, but does not teach its use in suppressing the immune system through activation of IL-27R (Remarks, p. 15, third paragraph). Applicant acknowledges that the citation of Bennett et al., at page 4, states "what anyone skilled in the art would know," that an agonist antibody can be used to activate an IL-27R (Remarks, p. 15, fourth paragraph). Applicant also acknowledges that Bennett et al., teach that the agonist antibody can be used to treat conditions in which an effective amount of WSX receptor [IL-27R] activation leads to therapeutic benefit (Remarks, p. 15, last paragraph). However, Applicant argues that the use of IL-27R agonists is not suggested for immune suppression (Remarks, p. 16, first paragraph). Applicant argues that the conditions recited on pages 56-59 reference immune suppression in patients using antagonists, not agonists, as presently claimed (Remarks, p. 16, second paragraph). Applicant argues that Bennett et al., "only vaguely alludes to a use for an agonists of IL-27R" for immune suppression (Remarks, p. 16, second paragraph). Applicant also states that the claims of the instant invention have been amended to recite disorders in which immune suppression is especially desired, but also states that "[a] patient may be

suffering from any of a wide range of disorders and be in need of immune suppression" (Remarks, p. 16, third paragraph). Applicant's arguments have been fully considered, but they are not persuasive.

Applicant's argument that Bennett et al., do not teach its use in suppressing the immune system through activation of IL-27R, is not supported in light of Applicant's own admission that "immune suppression" is typically a *de facto* part of "any definition of an immune related disease or disorder" (Remarks, p. 15, third paragraph) (compare Remarks, p. 14, last paragraph). Applicant's argument that Bennett et al., does not teach the "specific use" of an agonist for immune suppression is tantamount to arguing the intended use of the agonists. The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claims recite using an old composition or structure and the "use" is directed to a result or property of that composition or structure (i.e. as an agonist), then the claim is anticipated. In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). While the reference may not show a specific recognition of the claim result using the same language as the instant claims, it is implied and its discovery by Applicant is tantamount only to finding a property in the old composition. In re Tomlinson 363 F.2d at 934, 150 USPQ 623, at 628 (CCPA 1966). Applicant's admission that Bennett et al., teaches a use for agonists of IL-27R in immune suppression, even if Applicant's considers that teaching "vague" is accepted by the examiner as an admission that Bennett et al., teaches the use of agonists of IL-27R in methods of immune suppression.

With regard to Applicant's argument that the conditions recited on pages 56-59 reference immune suppression in patients using antagonists, not agonists, as presently claimed (Remarks, p. 16, second paragraph), Applicant recites one embodiment of using antagonists on page 56, line 34. However, several other embodiments are taught using anti-WSX receptor agonist antibodies (see p. 56, lines 13 and 24) which represent different embodiments and different uses. With regard to Applicant's statement that the claims of the instant invention have been amended to recite disorders in which immune suppression is especially desired, it is also noted that Applicant admits that "[a] patient may be suffering from any of a wide range of disorders and be in need of immune suppression" (Remarks, p. 16, third paragraph), thus rendering Applicant's argument moot. The instant claims remain anticipated.

12. Claims 1, 6, 11-13, 18-21, 24-26, and 73 remain rejected under 35 U.S.C. 102(e) as being anticipated by Matthews *et al.*, US Patent 7,074,397 B1 (11 July 2006, benefit to 8 January 1996), for the reasons of record and the reasons set forth herein.

Applicant argues that patients selected for treatment in the '397 patent would be selected based on their need for enhanced proliferation of blood cells (Remarks, p. 16, last paragraph). Applicant admits that the '397 patent lists some of the same diseases as in the present claims, but argues that the patients suffering from those diseases are selected because of their need for blood cell proliferation (Remarks, p. 17, first paragraph). Applicant argues that the teachings of the '397 patent do not explicitly state that activation of IL-27R can be used to suppress the immune system (Remarks, p. 17, second paragraph). Applicant's arguments have been fully considered, but they are not persuasive.

Applicant's arguments are rendered moot by Applicant's admissions that "[a] patient may be suffering from any of a wide range of disorders and be in need of immune suppression" (compare Remarks, p. 16, third paragraph) and that "immune suppression" is typically a *de facto* part of "any definition of an immune related disease or disorder" (compare Remarks, p. 14, last paragraph). The '397 patent teaches compositions and methods of use for agonist antibodies that bind to the WSX receptor (IL-27R) (column 3, lines 38-40, 46-47; column 14, lines 61-64, column 17, lines 14-16, column 44, line 22; column 80, lines 47-48 and 58-59; and column 45, beginning at line 36 to column 50) in the treatment of hematopoietic disorders, infections, and malignancies (column 50, lines 58-67 to column 51, lines 1-13). Applicant's definition of the patient population includes individuals with the same disorders taught by the '397 patent as being treatable with agonist antibodies that bind the WSX receptor (IL-27R) (see especially, column 50, lines 58-67 to column 51, lines 1-13) (compare claims 21 and 73, especially the listed disorders of: tumor metastasis, leukemia, multiple myeloma, myelogenous leukemia, septic shock, fever, Reiter's syndrome, enteropathic arthritis, Lyme disease, staphylococcal-induced arthritis, rheumatic fever, pemphigus, and an inflammatory condition resulting from infection). The instant claims remain anticipated.

New Claim Objections

13. Claims 21 and 73 are objected to because of the following informalities: claims 21 and 73 have multiple recitations of the same diseases and only one recitation is needed. For example, rheumatoid arthritis is listed on line 12, p. 4 of 19 (in the claims filed 10 December 2007) and also on line 25. Similarly, Sjogren's syndrome appears at line 16, bridging line 17 and also on line 26. Rheumatic fever is listed on both line 17 and on line 25. The list of disorders in claim 73 appears to be substantially duplicative of the list in claim 21 and the same duplications are also noted in claim 73. Appropriate correction is required.

New Claim Rejections

Provisional Obviousness-Type Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1, 6, 11-13, 18-23, and 73 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-24 and 26-28 of copending Application No. 11/880,121. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims teach a method of treating a patient comprising administering to the subject an IL-27R agonist. IL-27R is a heterodimeric cytokine receptor comprising WSX-1 and glycoprotein 130 (gp130) (see, for exemplary purposes only, UniProt Accession #Q6UWB1, IL27RA_human, 1998.) Together WSX-1 and gp130 constitute a signal-transducing receptor for IL-27. The IL-27R alpha subunit is also known as WSX-1, Type I T-cell cytokine receptor, TCCR, and protein CRL1 (see UniProt, #Q6UWB1, supra). The ligand for IL-27R, (which is considered an IL-27R agonist) is IL-27 a heterodimeric protein consisting of the p40-related protein Epstein-Barr virus-induced gene 3 (EBI3) non-covalently linked to an IL-12p35-related protein, p28 (also known as IL-30) (see, for

exemplary purposes only, Uniprot Accession #Q14213, IL-27B_human, 2002). Simply put, IL-27R = WSX-1/TCCR+gp130 and IL-27 =p28+EBI3.

The IL-27 ligands and IL-27R agonists taught by claims 21, 26, and 27 of the '121 application are the same as the IL-27 ligands and IL-27R agonists of the instant claims. The "human subjects" of the '121 application (compare claim 22 of the '121 application) are rendered obvious by the "patients" of the instant application. The disorders/conditions listed in claims 23 and 28 of the '121 application are recited in and/or overlap with the disorders/conditions listed in instant claims 21 and 73. The step of diagnosing the subject with the inflammatory condition prior to administering it in claim 24 of the '121 application is rendered obvious by the statement of administration in the instant claims that the patient be "in need thereof."

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Examiner, Art Unit 1647